

(1) The construction of the establishment in which the biological product is prepared is defective, or the establishment is not conducted as required by the regulations in parts 101 through 118 of this subchapter;

(2) The methods of preparation of the product are faulty, or the product contains impurities or lacks potency;

(3) The product is so labeled or advertised as to mislead or deceive the purchaser in any particular;

(4) The licensee, permittee, or the foreign manufacturer has failed to maintain and make available for inspection records in connection with the development and preparation of product, has failed to provide complete and accurate information when requested, or has failed to provide complete and accurate information in the Outline of Production or in reports and records;

(5) The licensee or permittee has violated or failed to comply with any provision of the Virus-Serum-Toxin Act or the regulations in this subchapter;

(6) The license or permit is otherwise used to facilitate or effect the preparation, sale, barter, exchange, shipment, or importation, contrary to the Virus-Serum-Toxin Act, of any worthless, contaminated, dangerous, or harmful biological product.

(b) In case of willfulness or where the public health, interest, or safety so required the Secretary may, without hearing, informally suspend such establishment license, product license, or permit upon the grounds set forth in paragraph (a) of this section pending determination of formal proceedings under part 123 of this subchapter for suspension or revocation of the license or permit.

[38 FR 23512, Aug. 31, 1973, as amended at 41 FR 44359, Oct. 8, 1976; 61 FR 52874, Oct. 9, 1996; 64 FR 43044, Aug. 9, 1999]

§ 105.2 Notification of infractions.

If an infraction of a requirement of a product license is brought to the attention of the licensee by written notification thereof by Animal and Plant Health Inspection Service, a subsequent violation of similar nature occurring with the same licensed biological product within 6 months of the said written notification shall be prima facie evidence of willful violation

and the license for the product shall be subject to suspension or revocation under the provisions of § 105.1(b).

[42 FR 31430, June 21, 1977, as amended at 56 FR 66783, Dec. 26, 1991]

§ 105.3 Notices re: worthless, contaminated, dangerous, or harmful biological products.

(a) If at any time it appears that the preparation, sale, barter, exchange, shipment, or importation, as provided in the Virus-Serum-Toxin Act, of any biological product by any person holding a license or permit may be dangerous in the treatment of domestic animals, the Secretary may without hearing notify the licensee or permittee, and pending determination of formal proceedings instituted under part 123 of this subchapter for suspension or revocation of the license or permit insofar as it authorizes the manufacture or importation of the particular product, no person so notified shall thereafter so prepare, sell, barter, exchange, ship, deliver for shipment, or import such product.

(b) If a serial of biological product is found to be unsatisfactory according to applicable Standard Requirements, the Administrator may notify the licensee to stop distribution and sale of the serial.

(c) When notified to stop distribution and sale of a serial or subserial of a veterinary biological product under the provisions of paragraph (a) or (b) of this section, veterinary biologics licensees or permittees shall:

(1) Stop the preparation, distribution, sale, barter, exchange, shipment, or importation of the affected serial(s) or subserial(s) of any veterinary biological product pending further instructions from APHIS.

(2) Immediately, but no later than 2 days, send stop distribution and sale notifications to any wholesalers, jobbers, dealers, foreign consignees, or other persons known to have any such veterinary biological product in their possession, which instruct them to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any such veterinary biological product. All notifications shall be documented in writing by the licensee or permittee.

§ 105.4

(3) Account for the remaining quantity of each serial(s) or subserial(s) of any such veterinary biological product at each location in the distribution channel known to the manufacturer (licensee) or importer (permittee).

(4) When required by the Administrator, submit complete and accurate reports of all notifications concerning stop distribution and sale actions to the Animal and Plant Health Inspection Service pursuant to §116.5 of this subchapter.

(Approved by the Office of Management and Budget under control number 0579-0318.)

[38 FR 23512, Aug. 31, 1973, as amended at 56 FR 66783, Dec. 26, 1991; 72 FR 17798, Apr. 10, 2007]

§ 105.4 Termination of licenses and permits for inactivity.

(a) If a biological product has not been prepared by a licensee, or imported by a permittee for a period of 5 years or more, the Administrator may require the licensee to show intent to resume production, or the permittee to show intent to resume importation, within 6 months of notification. If the licensee does not resume preparation, or the permittee does not resume importation, within 6 months of notification, or within a mutually agreeable period, the product license, or permit, may be terminated by the Administrator.

(b) When a license or permit is terminated, the licensee or permittee shall continue to be subject to the applicable records provisions of § 116.8.

[61 FR 52874, Oct. 9, 1996]

PART 106—EXEMPTION FOR BIOLOGICAL PRODUCTS USED IN DEPARTMENT PROGRAMS OR UNDER DEPARTMENT CONTROL OR SUPERVISION

AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

§ 106.1 Biological products; exemption.

The Administrator may exempt any biological product from one or more of the requirements of this subchapter if he determines that such product will be used by the Department or under

9 CFR Ch. I (1-1-11 Edition)

the supervision or control of the Department in the prevention, control or eradication of animal diseases in connection with (a) an official USDA program; or (b) an emergency animal disease situation, or (c) a USDA experimental use of the product.

[45 FR 65184, Oct. 2, 1980, as amended at 56 FR 66783, Dec. 26, 1991]

PART 107—EXEMPTIONS FROM PREPARATION PURSUANT TO AN UNSUSPENDED AND UNREVOKED LICENSE

Sec.

107.1 Veterinary practitioners and animal owners.

107.2 Products under State license.

AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

§ 107.1 Veterinary practitioners and animal owners.

Products prepared as provided in paragraphs (a) and (b) of this section and establishments in which such products are prepared, shall be exempt from preparation pursuant to unsuspended and unrevoked establishment and product licenses. Persons exempt from licensure under this part shipping products which contain live organisms shall provide any information the Administrator may require prior to shipment, or at any other time deemed necessary, in order to assess the products' safety and effect on the environment. The shipment or delivery for shipment anywhere in or from the United States of any exempted product which is worthless, contaminated, dangerous, or harmful is prohibited, and any person shipping such product, or delivering such product for shipment, shall be subject to sanctions under the Act.

(a)(1) Products prepared by a veterinary practitioner (veterinarian) solely for administration to animals in the course of a State licensed professional practice of veterinary medicine by such veterinarian under a veterinarian-client-patient relationship and establishments in which such products are prepared shall be exempt from licensing under the Act and regulations. Such a relationship is considered to exist when: